



(주)그린메탈
Green Metal Co., Ltd.

Sterility test Isolator Specifications





Basic specifications

1. Inside Chamber - STS316L 3T (Posco)
2. External Casing - STS304 2T (Posco)
3. Airflow - Vertical laminar air flow (Standard: 0.45m/s)
4. HEPA Filter - 99.99% efficient at 0.3 microns
5. HEPA Filter Protection Net - Mesh Screen (#200)
6. Lighting - LED: embedded in the mesh screen
7. Gloves - 10" Oval Acetal
8. Pressure - 25Pa \pm 10Pa during Sterility Testing

2 COMPONENT RELATED

1. VHP module - self-manufactured by green metal, automatic desiccant drying system, large-capacity H₂O₂ container
2. PLC - Manufacturer: Siemens, Model: S7-1200 Series
3. HMI - Manufacturer: Siemens, Model Name: TP1200 Series
4. H₂O₂ Meter - Manufacturer: Dräger, Model: Polytron® 7000 (H₂O₂ HC , H₂O₂ LC)
5. Digital Differential Pressure Gauge - Manufacturer: Dwyer, Model: 616KD-B-13, Measuring range: 0-1250Pa, Error range \pm 1%
6. Digital thermo-hygrometer - Manufacturer: Vaisala, Model: HMP-110, Error range \pm 1.5%
7. Digital Anemometer - Manufacturer: E+E, Model Name: EE680 (H₂O₂ anti-corrosion coating model)
Material: Stainless steel, Measuring range: Max 2m/s (only for trace measurement)
8. Particle Counter - Manufacturer: TSI USA
9. Air Sampler - Manufacturer: TSI USA

3 Alarm related

1. Alarm message display (popup) & buzzer
2. Display the action screen when checking the alarm
3. Alarm history backup to USB (authorization setting)

4 Log & back up

1. Logging of various data
2. Save and backup as Excel file or PDF file
3. Save VHP Cycle Recipe
4. Saving and outputting result report as PDF file after sterilization
5. 21 CFR Part 11 Compliance

5 Glove Leak Tester

3. Including installation and commissioning
2. Data storage and report output - PDF storage, dot printer output
3. 21 CFR Part 11 Compliance